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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|----------------------|---------------------|------------------|
| 10/582,355 | 06/09/2006 | Masayoshi Esashi | 062648 | 1537 |
| 38834 | 7590 | 12/22/2009 | EXAMINER | |
| WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036 | | | | CHEN, VICTORIA W |
| 3739 | | ART UNIT | | PAPER NUMBER |
| | | NOTIFICATION DATE | | DELIVERY MODE |
| | | 12/22/2009 | | ELECTRONIC |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentmail@whda.com

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/582,355 | ESASHI ET AL. | |
| | Examiner | Art Unit | |
| | VICTORIA W. CHEN | 3739 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 10 December 2009.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-24 is/are pending in the application.
 4a) Of the above claim(s) 6 and 17 is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-5, 7-16 and 18-24 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 09 June 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/9/06, 10/3/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of claims 1-5, 7-16 and 18-24 in the reply filed on 12/10/09 is acknowledged.

Drawings

Figure 22 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). Corrected drawings in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: pg. 2, ln. 35 of the specification refers to "Non-Patent Reference 1". This is improper because it is unclear as to which reference this is referring since multiple IDS have been filed for the application with multiple non patent literature references.

Appropriate correction is required.

Claim Objections

Claims 1-3, 7-13 and 18-24 are objected to because of the following informalities:

Claim 2 recites "and said tip is comprises" in ln. 2, which should be changed to –and said tip comprises--.

Claim 3 recites "covers inflatable" in ll. 2-3, and is suggested to be changed to --
inflatably covers--.

Claim 14 recites "covers inflatable" in ll. 2-3, and is suggested to be changed to --
inflatably covers--.

Claims 1, 2, 7-13 and 18-23 contain the acronyms "SMA" and "LED". These should be replaced by their respective full phrases so there is no ambiguity or possible misinterpretation of what the acronyms stand for.

Claims 7, 8, 12, 19, 23 and 24 have preambles in which they are dependent on unelected claims. These dependencies are no longer valid, and should be removed.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 8-11 and 19-22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 8 recites the limitation "each small diameter hole" in ln. 8. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the behind link" in ln. 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 10 recites the limitation "the front link" in ln. 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 19 recites the limitation "each small diameter hole" in ln. 9. There is insufficient antecedent basis for this limitation in the claim.

Claim 21 recites the limitation "the behind link" in ln. 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 21 recites the limitation "the front link" in ln. 3. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4, 5, 7-13, 15, 16 and 18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Takehana et al. (US 4930494).

Regarding claim 1, Takehana discloses an active tube, wherein it comprises; a working channel tube [Fig. 59] the inside of which is used as a working channel [233]; an SMA coil [227] arranged along said working channel tube; one or more weights [251, col. 23, ll. 12-15, knurls can be attached to outer periphery of protecting tube which corresponds to element 234 in Fig. 59] attached on the outer surface of the combined working channel tube and SMA coil and an outer skin tube [240] covering the outer surface of said working channel tube and said SMA coil [Fig. 59].

Regarding claim 2, Takehana discloses an active tube, wherein it comprises a tip [223] and a main tube [222] connected to said tip, and said tip comprises: a working channel tube [Fig.

59] connected through to said main tube; a bending mechanism [223] to support said working channel tube and to bend said working channel tube; one or more weights [251, col. 23, ll. 12-15, knurls can be attached to outer periphery of protecting tube which corresponds to element 234 in Fig. 59] attached on the outer surface of said bending mechanism; an outer skin tube [240] covering the outer surface of said bending mechanism together with said weight, wherein said bending mechanism includes an SMA coil [227] arranged in the longitudinal direction of said working channel tube [Fig. 59].

Regarding claims 4 and 5, Takehana discloses an endoscope is built into said tip, or alternatively can be interpreted as being inserted into said working channel tube of said tip [col. 22, ll. 14-17].

Regarding claim 7, Takehana discloses the front end of the endoscope is provided with an image input part comprising an optical fiber or an image pickup device and a light guide for illumination or LED to illuminate the forward of said image input part [col. 22, ll. 44-50].

Regarding claim 8, Takehana discloses said bending mechanism is provided with a pair of links [225, 226] attached at an interval to said working channel tube [Fig. 59]; and an outer skin [240] contacted to said pair of links and covering said working channel tube; and an air layer is formed with said pair of links and the outer surface of said working channel tube [Fig. 59], and said SMA coil is inserted through each small diameter hole [228] of said pair of links to be wired to said air layer.

Regarding claim 9, Takehana discloses said SMA coil is inserted through a first small diameter hole of a behind link and a first small diameter hole of a front link, bent back at the

front end of said front link, inserted through a second small diameter hole of said front link and a second small diameter hole of said behind link, and is wired [Fig. 62].

Regarding claim 10, Takehana discloses said SMA coil is inserted through each small diameter hole of the behind link and each small diameter hole of the front link between said pair of links, bent back a plurality of times, and is wired [Fig. 62].

Regarding claim 11, Takehana discloses a plurality of said SMA coils are provided at equal intervals with respect to the central axis of said working channel tube between said pair of links [Fig. 61].

Regarding claim 12, Takehana discloses said main tube is provided along the axis of said main tube with a working channel [within 224] connected through to said working channel tube [Fig. 59] and a wiring channel [interior of 224] to insert the wire [237] to be connected to the SMA coil of said bending mechanism.

Regarding claim 13, Takehana discloses an active tube system, wherein it comprises an active tube [Fig. 59], a control box [9] to control a bending mechanism of said active tube, and a control input part [7] to input the control information for said bending mechanism to said control box; and said active tube comprises a tip [223] and a main tube [222] connected to said tip, and said tip comprises: a working channel tube [Fig. 59] connected through to said main tube; a bending mechanism [223] to support said working channel tube and to bend said working channel tube; one or more weights [251, col. 23, ll. 12-15, knurls can be attached to outer periphery of protecting tube which corresponds to element 234 in Fig. 59] attached on the outer surface of said bending mechanism; an outer skin tube [240] covering the outer surface of said

bending mechanism together with said weight, wherein said bending mechanism includes an SMA coil [227] arranged in the longitudinal direction of said working channel tube [Fig. 59].

Regarding claims 15 and 16, Takehana discloses an endoscope is built into said tip, or alternatively can be interpreted as being inserted into said working channel tube of said tip [col. 22, ll. 14-17].

Regarding claim 18, Takehana discloses the front end of the endoscope is provided with an image input part comprising an optical fiber or an image pickup device and a light guide for illumination or LED to illuminate the forward of said image input part [col. 22, ll. 44-50].

Regarding claim 19, Takehana discloses said bending mechanism is provided with a pair of links [225, 226] attached at an interval to said working channel tube [Fig. 59]; and an outer skin [240] contacted to said pair of links and covering said working channel tube; and an air layer is formed with said pair of links and the outer surface of said working channel tube [Fig. 59], and said SMA coil is inserted through each small diameter hole [228] of said pair of links to be wired to said air layer.

Regarding claim 20, Takehana discloses said SMA coil is inserted through a first small diameter hole of a behind link and a first small diameter hole of a front link, bent back at the front end of said front link, inserted through a second small diameter hole of said front link and a second small diameter hole of said behind link, and is wired [Fig. 62].

Regarding claim 21, Takehana discloses said SMA coil is inserted through each small diameter hole of the behind link and each small diameter hole of the front link between said pair of links, bent back a plurality of times, and is wired [Fig. 62].

Regarding claim 22, Takehana discloses a plurality of said SMA coils are provided at equal intervals with respect to the central axis of said working channel tube between said pair of links [Fig. 61].

Regarding claim 23, Takehana discloses said main tube is provided along the axis of said main tube with a working channel [within 224] connected through to said working channel tube [Fig. 59] and a wiring channel [interior of 224] to insert the wire [237] to be connected to the SMA coil of said bending mechanism.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 3, 14 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takehana as applied to claims 2 and 13 above, in view of McCoy (US 5114402).

Regarding claims 3 and 14, Takehana teaches the invention as claimed, including a main tube, but fails to teach a cylindrical thin film covering the outer surface of the main tube and the main tube being provided with a balloon inflating channel to supply gas or liquid into the space between said main tube and thin film, thereby said thin film is inflated to form a balloon. McCoy teaches a bendable endoscope [70] comprising shape memory coils with a balloon (e.g. cylindrical thin film) covering the endoscope tube for anchoring the endoscope within a desired location in a body cavity [col. 7, ll. 44-60]. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the active tube with a balloon on the main tube to provide the advantage of anchoring the endoscope within a desired location in a body cavity.

Regarding claim 24, Takehana teaches a control input part [7] which is manually operable by the user, but fails to specifically teach the control input part being a control stick with a formed grip and provided with a slide type operation mechanism that can be grabbed with a palm. McCoy teaches a control unit [30] having a control stick [34] for controlling the bending action of the endoscope. McCoy further teaches that various types of control devices can be employed [col. 6, ll. 5-18]. Since both Takehana teaches steerable endoscopes having control input parts for controlling the bending of the endoscope, it would have been obvious to one of ordinary skill to substitute one for the other to achieve the predictable result of controlling the bending of the endoscope. It is noted that applicant's specification fails to provide any criticality and/or unexpected result associated with the claimed control input device. Therefore the examiner maintains that one of ordinary skill in the art would obviously recognize that any reasonable kind of control input part may be used to achieve the desired results.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

| | | | |
|-------------------|----------|----------------------------|--|
| US 20040193140 A1 | US-PGPUB | Griffin, Stephen et al. | Medical device |
| US 6425418 B1 | USPAT | Maeda; Shigeo et al. | Flexible tube and manufacturing method for the same |
| US 4610673 A | USPAT | Russo; Ronald D. | Gastroenteric feeding tube |
| US 6764441 B2 | USPAT | Chiel; Hillel J. et al. | Peristaltically self-propelled endoscopic device |
| US 5810717 A | USPAT | Maeda; Shigeo et al. | Bending mechanism and stereoscope using same |
| US 5645520 A | USPAT | Nakamura; Yoshihiko et al. | Shape memory alloy actuated rod for endoscopic instruments |
| US 4977886 A | USPAT | Takehana; Sakae et al. | Position controlling apparatus |
| US 4516970 A | USPAT | Kaufman; Jack W. et al. | Medical device |
| US 5354518 A | USPAT | Okada; Yosuke et al. | Method for manufacturing a fiberscopic catheter |

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA W. CHEN whose telephone number is (571)272-3356. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victoria W Chen/
Examiner, Art Unit 3739

/John P Leubecker/
Primary Examiner, AU 3739